



This document is scheduled to be published in the Federal Register on 12/31/2014 and available online at <http://federalregister.gov/a/2014-30307>, and on FDsys.gov

DEPARTMENT OF DEFENSE

BILLING CODE 5001-06

Office of the Secretary

32 CFR Part 199

[DOD–2013–HA–0164]

RIN 0720-AB61

TRICARE; Coverage of Care Related to Non-Covered Initial Surgery or Treatment

AGENCY: Office of the Secretary, Department of Defense

ACTION: Final rule.

SUMMARY: This final rule revises the limitations on certain TRICARE basic program benefits. More specifically, it allows coverage for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae), as well as medically necessary and appropriate follow-on care, resulting from a non-covered incident of treatment provided pursuant to a properly granted Supplemental Health Care Program waiver. This final rule amends two provisions of the TRICARE regulations which limits coverage for the treatment of complications resulting from a non-covered incident of treatment, and which expressly excludes from coverage in the Basic Program services and supplies related to a non-covered condition or treatment.

DATES: This final rule is effective [INSERT 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Thomas Doss (703) 681-7512.

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Purpose of Regulatory Action

Need for the Regulatory Action

This final rule is necessary for consistency with existing regulatory provisions and to protect TRICARE beneficiaries from incurring unnecessary financial hardships arising from the current regulatory restrictions that prohibit TRICARE coverage of the treatment of complications resulting from certain non-covered medical procedures. On occasion, an authorized official of a uniformed service may request from the Director, Defense Health Agency (DHA) a waiver of TRICARE regulatory restrictions or limitations, when the waiver is necessary to assure adequate availability of health care services to the active duty member. In those cases when a waiver has been properly granted under § 199.16(f), this rule grants benefits coverage for otherwise covered services and supplies required for treating complications arising from the non-covered incident of treatment provided in the private sector pursuant to the waiver. Additionally, with respect to care that is related to a non-covered initial surgery or treatment, the final rule seeks to eliminate any confusion regarding what services and supplies will be covered by TRICARE and under what circumstances they will be covered.

Legal Authority for the Regulatory Action

This regulation is finalized under the authorities of 10 U.S.C. 1073, which authorizes the Secretary of Defense to administer the medical and dental benefits provided in 10 U.S.C. chapter 55. The Department is authorized to provide medically necessary and appropriate treatment for mental and physical illnesses, injuries and bodily malfunctions, including hospitalization, outpatient care, drugs, treatment of medical and surgical conditions and other types of health care outlined in 10 U.S.C. 1077(a). Although section 1077 defines benefits to be provided in the Military Treatment Facilities (MTFs), these

benefits are incorporated by reference into the benefits provided in the civilian health care sector to active duty family members and retirees and their dependents through sections 1079 and 1086 respectively.

B. Summary of the Final Rule

The final rule amends the existing special benefit provision regarding complications (unfortunate sequelae) resulting from non-covered initial surgery or treatment, to more clearly address what services and supplies will be covered by TRICARE and under what circumstances they will be covered. The provision itself is relabeled “Care related to non-covered initial surgery or treatment” to eliminate any confusion regarding what constitutes a complication or unfortunate sequelae and how broadly or narrowly the exclusion and exceptions to the exclusion should be applied. As amended, the regulatory section will specifically address coverage of otherwise covered medically necessary treatment, to include coverage of (i) treatment of complications that represent a separate medical condition; (ii) treatment of complications and necessary follow-on care resulting from a non-covered incident of treatment provided in an MTF; and (iii) treatment of complications and necessary follow-on care resulting from a non-covered incident of treatment provided pursuant to an approved Supplemental Health Care Program (SHCP) waiver. Additionally, the regulatory exclusion at § 199.4(g)(63) is amended to state clearly that all services and supplies related to a non-covered condition or treatment, including any necessary follow-on care and treatment of complications, are excluded from coverage except as provided in § 199.4(e)(9).

C. Costs and Benefits

This final rule is not anticipated to have an annual effect on the economy of \$100 million or more, making it a non-economically significant rule under Executive Order 12866 and non-major rule under the Congressional Review Act. All services and supplies authorized under the TRICARE Basic Program must be determined to be medically necessary in the treatment of an illness, injury or bodily malfunction before the care can be cost shared by TRICARE. For this reason, DoD anticipates that TRICARE will incur only a marginal increase in cost associated with the inclusion of coverage for treatment of complications and necessary follow-on care for TRICARE beneficiaries who received previously authorized non-covered treatment pursuant to a SHCP waiver while on active duty.

I. Background

A. Statutory and Regulatory Background

Members of the uniformed services on active duty are entitled to medical and dental care pursuant to 10 U.S.C. 1074, including the provision of such care in private facilities. With respect to the purchase of private sector health care services for Active Duty Service Members (ADSMs) under the SHCP, § 199.16 implements the statutory provision at 10 U.S.C. 1074(c). Generally, the same rules that govern payment and administration of private sector health care claims under TRICARE apply to the SHCP and the care that members receive in private facilities is comparable to coverage for medical care under the TRICARE Prime program. Section 199.16(f) provides the Director of DHA discretionary authority to waive requirements of TRICARE regulations, including any restrictions or limitations under the TRICARE Basic Program benefits,

except those specifically set forth in statute, based on “a determination that such waiver is necessary to assure adequate availability of health care to Active Duty members.”

ADSMs have access to non-covered care including experimental or unproven medical care and treatments in the purchased care sector on a case-by-case basis using the SHCP waiver process. The Director, DHA, or designee specifically approves these case-by-case treatment decisions, resulting in a number of ADSMs receiving otherwise non-covered private sector care while serving.

If an ADSM is granted a waiver under the SHCP to receive an otherwise non-covered incident of treatment by a private sector provider, rather than in an MTF, and suffers complications from the care, SHCP funds can be used to cover necessary follow-on care and treatment of complications in the purchased care system as long as the member remains on active duty. Once the member retires, however, SHCP coverage no longer exists and TRICARE does not cover unfortunate sequelae of non-covered care provided in the purchased care sector, except in limited circumstances (e.g. later complications that represent a separate medical condition separate from the condition that the non-covered treatment or surgery was directed toward, and the treatment of the complication is not essentially similar to the covered procedures. This may include a systemic infection, cardiac arrest, or acute drug reaction). Additionally, once the service member has retired, existing regulations would not allow the continuation of any needed follow-on care such as rehabilitative care or drug therapy. When these beneficiaries require such treatment, they are responsible for the payment for this necessary treatment, which may result in significant financial hardship.

This rule resolves that unfortunate situation by allowing coverage of treatment for necessary follow-on care, including complications, resulting from non-covered treatment provided to beneficiaries pursuant to a SHCP waiver. The specific procedures for approval of this treatment will be addressed in the TRICARE Policy Manual to ensure that this information is current and easily accessible. TRICARE manuals may be accessed at <http://www.tricare.mil>.

B. Summary of the Proposed Rule

We proposed to amend the existing special benefit provision regarding complications (unfortunate sequelae) resulting from non-covered initial surgery, to more clearly address what services and supplies will be covered by TRICARE and under what circumstances they will be covered. We also proposed to re-label the regulatory provision to read: “Care related to non-covered initial surgery or treatment” to eliminate any confusion regarding what constitutes a complication or unfortunate sequelae and how broadly or narrowly the exclusion and exceptions to the exclusion would be applied. As amended, the regulatory section would specifically address coverage of otherwise covered medically necessary treatment, to include (i) coverage of complications that represent a separate medical condition; (ii) treatment of complications and necessary follow-on care resulting from a non-covered incident of treatment provided in an MTF; and (iii) treatment of complications and necessary follow-on care resulting from a non-covered incident of treatment provided pursuant to an approved SHCP waiver. Inclusion of the third prong would support the provision of care necessary to allow members to return to full duty and/or reach their maximum rehabilitative potential without requiring the member to bear the sole financial risk for unfortunate sequelae once they are no longer on

active duty. This amendment would also provide consistent treatment of unfortunate sequelae and necessary follow-on care when an original episode of non-covered care is provided for a valid governmental purpose, whether to support Graduate Medical Education (GME) and maintain provider skill levels within an MTF or an ADSM's fitness for duty through authorization of the purchase of otherwise non-covered care via an SHCP waiver. Additionally, we proposed to amend the regulatory exclusion at § 199.4(g)(63) to clearly state that all services and supplies related to a non-covered condition or treatment, including any necessary follow-on care and treatment of complications, would be excluded from coverage except as provided in § 199.4(e)(9).

C. Summary of the Final Rulemaking

Modifications to the TRICARE Basic Program Benefits

Under the TRICARE private sector health care program, certain conditions and treatments are excluded from coverage. For example, any drug, device, medical treatment, or procedure whose safety and efficacy has not been established by reliable evidence is considered unproven and excluded from coverage. This exclusion includes all services directly related to the unproven drug, device, medical treatment or procedure. Specifically, benefits for otherwise covered services and supplies that are required in the treatment of complications (unfortunate sequelae) resulting from a non-covered incident of treatment, are generally excluded from TRICARE coverage pursuant to § 199.4(e)(9), unless the complication represents a separate medical condition such as a systemic infection, cardiac arrest, and acute drug reaction. TRICARE also excludes any needed follow-on care resulting from a non-covered condition or initial surgery or treatment pursuant to § 199.4(g)(63).

There is currently one exception to this general exclusion, found at § 199.4(e)(9)(ii), which allows coverage of otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) resulting from a non-covered incident of treatment provided in a MTF, when the initial non-covered service has been authorized by the MTF Commander and the MTF is unable to provide the necessary treatment of the complications. This current exception recognizes that in order to support GME and maintain provider skill levels, MTF providers are required to perform medical procedures that may be excluded from coverage under the TRICARE private sector program. This coverage provision was viewed as necessary to protect TRICARE beneficiaries from incurring financial hardships in such cases.

Currently, Active Duty Service Members (ADSMs) may receive non-covered TRICARE private sector health care services under the SHCP if a waiver is submitted through the Service and approved by the Director, DHA, or designee, in accordance with § 199.6(f). While the Department wants to ensure that Service members have access to the latest, promising medical technologies and procedures, there must be assurance that the care is safe and effective, and that members are not subjected to undue risk, or rendered unfit for continued service, due to complications suffered because of unproven medical care. Consequently, requests for non-covered procedures and treatments, including unproven care, are carefully reviewed in conjunction with other available, proven treatments, if any exist, to determine whether approval of the requested care is necessary to assure the adequate availability of health care to the member. Currently, Service members are counseled that the treatment remains a non-covered TRICARE benefit, and that any follow-on care, including care for complications, will not be covered

by TRICARE once the member separates or retires. Members are left to make a difficult choice between pursuing a SHCP waiver in an effort to remain fit for full duty while assuming the financial risk of any necessary follow-on care after discharge, or, electing not to receive the care and risk separation from the Service.

Like the existing exception at § 199.4(e)(9)(ii) for non-covered care provided in a MTF, this exception is narrowly tailored to serve a similar government interest; namely, protecting former active duty members who have received private sector care pursuant to a SHCP waiver in an effort to ensure their fitness for duty and continued service.

Additionally, some confusion has arisen regarding the terms “complication” and “unfortunate sequelae” as these terms are not currently defined in regulation. Questions have arisen with respect to whether necessary follow-on care resulting from a non-covered procedure or treatment in an MTF is covered in situations where the MTF is unable to provide the necessary treatment. The intent of the prior September 16, 2011, final rule, as well as this final rule, is to protect TRICARE beneficiaries from incurring financial hardships in limited circumstances, which serve valid governmental purposes. Absent an exception to the general exclusion from coverage, treatment of adverse outcomes, both expected and unexpected, as well as any necessary follow-on care that is a direct result of the initial non-covered treatment, are excluded and could result in less than optimal care (e.g., not receiving necessary physical therapy following surgery) and/or a significant financial hardship for the beneficiary. The Agency did not intend to prevent coverage of necessary follow-on private sector care in situations where an MTF is unable to provide that care but the current regulatory language is subject to such a narrow interpretation absent additional clarification. This final rule permits coverage of

necessary continued treatment, such as physical therapy following a non-covered surgical procedure in an MTF. It also covers medically necessary follow-on care, including, for example, anti-rejection medications for former members who have received face and hand transplants. This rule eliminates the need to try to determine whether the medically necessary and appropriate care the patient is seeking from the private sector is considered treatment of an expected complication, an unexpected complication or routine follow-on care, because it will be clearly covered.

II. Summary of and Responses to Public Comments

The proposed rule was published in the Federal Register (78 FR 62506) October 22, 2013, for a 60-day comment period. We received comments on the proposed rule from three commenters.

Comments: Two commenters expressed general support for TRICARE expressly covering otherwise medically necessary treatment resulting from a non-covered incident of treatment provided pursuant to an approved SHCP waiver. They supported the policy objective of reducing financial risk for unfortunate sequelae once service members are no longer on active duty. One commenter stated further that TRICARE should cover all of the medical procedures that beneficiaries need. The second commenter, in addition to expressing support for the proposed change, emphasized the need for a properly approved SHCP waiver.

Response: We appreciate the commenters' support of this regulatory proposal. We would note that the comment pertaining to coverage of all medical procedures that beneficiaries need exceeds the scope of this Final Rule. Moreover, current TRICARE regulations already address those circumstances under which TRICARE is statutorily authorized to

provide coverage. We also point out that the Defense Health Agency issues waivers infrequently and with careful consideration to ensure that the member has access to medically necessary treatment. In these circumstances, SHCP waivers are only issued when necessary to ensure that health care services are adequately available to active duty service members.

Comment: One commenter observed that the Proposed Rule deleted the reference to “transsexual surgery” and “repair of a prolapsed vagina in a biological male who had undergone transsexual surgery” in the regulation text for § 199.4(e)(9)(i). The commenter queried whether we were proposing a change in policy regarding transsexual procedures.

Response: The proposed deletions in the regulation text of the proposed rule were intended to be strictly stylistic and not intended to reflect any change in policy regarding transsexual procedures. TRICARE continues not to cover transsexual surgery and consequently would not cover complications similar to the initial episode of non-covered care, such as the repair of a prolapsed vagina in a biological male who had undergone transsexual surgery. The statutory prohibition at 10 U.S.C. 1079(a)(12) continue to apply. The one, very limited exception to this general exclusion is that TRICARE may cover surgery and related medically necessary services performed to correct sex gender confusion (that is, ambiguous genitalia) which has been documented to be present at birth.

In the proposed rule, we acknowledged that some confusion had arisen in the industry regarding the terms “complication” and “unfortunate sequelae” because the terms were not defined in regulation. While not defining the terms in the regulation text,

we did further explain and clarify the intended scope of excluded treatment of complications and unfortunate sequelae resulting from non-covered initial surgery or treatment, to include expected and unexpected complications, as well as any necessary follow-on care that is a direct result of the initial non-covered treatment, absent an exception to the exclusion. We explained that in § 199.4(e)(9)(ii), for instance, the Agency did not intend to prevent coverage of necessary follow-on private sector care in situations where an MTF was unable to provide that care but the MTF Commander had authorized the initial noncovered service. To clarify the intended scope of the excluded treatment of complications or unfortunate sequelae, this rule adds “including any necessary follow-on care or the treatment of complications” in § 199.4(g)(63), and “and any necessary follow-on care” in § 199.4(e)(9)(ii).

Comment: We received one comment supporting our amendments to the regulations which clarify that the treatment of complications or unfortunate sequelae includes necessary follow-on care. The commenter felt that the Agency should withhold coverage of treatment for secondary complications when the initial procedure was purely elective and did not serve a legitimate national defense purpose. The commenter also recommended the adoption of a regulatory definition of “complication,” relying perhaps on a definition of the term used by private health insurers.

Response: We appreciate the commenter’s support of our clarifying amendments to the two regulatory provisions. While we will take under advisement proposing a regulatory definition of “complication” in the future, at this time we believe that the amendments in this rule will be adequate to clarify our intended meaning of the term and allow us to retain the necessary flexibility when implementing these regulations. The Agency is also

reluctant to classify levels of “complications” as primary or secondary, or consider the purpose for which non-covered treatment was provided. These proposals would add an unnecessary degree of complexity to this regulatory structure, or alternatively, would require the Agency to exceed the bounds of its statutory authority.

Comment: A commenter recommended that the Agency specifically exclude certain initial procedures from TRICARE coverage.

Response: This comment exceeds the scope of this final rule, and we will therefore not exclude from TRICARE coverage any initial procedures specified in the comment.

As a final matter, we are finalizing corrections in the regulatory text for § 199.4(e)(9)(ii) and (iii), including substituting references to the Director, DHA, in lieu of the Director, TMA, and the change from “§ 199.6(f) of this chapter” to “§ 199.16(f)” in § 199.4(e)(9)(iii). We are making the first non-substantive change for consistency with recent changes to the structure of the DoD. Section 731 of the National Defense Authorization Act for FY 2013 directed the Secretary of Defense to develop a plan carry out the reforms of the governance of the military health system, previously outlined in a March 2, 2012, Deputy Secretary of Defense memorandum. As described in a March 11, 2013, Deputy Secretary of Defense memorandum, the centerpiece of the governance reform was the establishment of a Defense Health Agency (DHA) which would, among other responsibilities, assume the designated functions of the TMA, which was being disestablished. Subsequently, the Department of Defense published Directive 5136.13 (published September 30, 2013), which provided that any reference in law, rule, regulation, or issuance to TMA will be deemed to be a reference to DHA, unless otherwise specified by the Secretary of Defense, and further, that the Director, DHA, will

serve as the program manager for TRICARE health and medical resources, as directed by the ASD(HA) and within the established MHS governance process. The reference to Director, DHA, in these two regulatory sections will clarify the provisions and ensure consistency with the current meaning of the existing regulations. The second non-substantive change clarifies a cross reference to “§ 199.16(f).” The proposed rule inaccurately referred to “§ 199.16(f) of this chapter.” In our view, these textual corrections do not constitute a rulemaking that would be subject to the APA notice and comment or delayed effective date requirements.

Provisions of the Final Rule

Because all comments that were within the scope of this rulemaking supported the proposed regulation changes, we are finalizing the proposed rule, with the exception of the non-substantive text corrections discussed above. The final rule amends the existing special benefit provision regarding complications (unfortunate sequelae) resulting from non-covered initial surgery. It re-labels the regulatory provision to read: “Care related to non-covered initial surgery or treatment.” It amends § 199.4(e)(9) to provide coverage for otherwise covered services and supplies required in the treatment of complications resulting from a noncovered incident of treatment: (i) but only if the later complication represented a separate medical condition; or (ii) if the noncovered incident of treatment was provided in an MTF, had been authorized by the MTF Commander, and the MTF was unable to provide the necessary treatment of the complications; or (iii) if the noncovered incident of treatment was provided in the private sector pursuant to a properly granted waiver under § 199.16(f). This final rule also amends the regulatory exclusion at § 199.4(g)(63) to state that all services and supplies related to a non-covered

condition or treatment, including any necessary follow-on care and treatment of complications, will be excluded from coverage except as provided in §199.4(e)(9).

III. Regulatory Procedure

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”

It has been determined that this final rule is not a significant regulatory action. This rule does not:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in these Executive Orders.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104-4)

It has been determined that this final rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

Pub.L. 96-354, “Regulatory Flexibility Act” (5 U.S.C. 601)

It has been certified that this final rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Set forth in the final rule are minor revisions to the existing regulation. The DoD does not anticipate a significant impact on the Program.

Pub.L. 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

It has been determined that this final rule does not impose reporting or recordkeeping requirements under the Paperwork Act of 1995.

Executive Order 13132, Federalism

It has been determined that this final rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

- (1) The States;
- (2) The relationship between the National Government and the States; or
- (3) The distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, and Military personnel.

Accordingly, 32 CFR Part 199 is amended to read as follows:

Part 199-- [AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.4 is amended by revising paragraphs (e)(9) and (g)(63) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(e) * * *

(9) Care related to non-covered initial surgery or treatment. (i) Benefits are available for otherwise covered services and supplies required in the treatment of complications resulting from a non-covered incident of treatment (such as nonadjunctive dental care or cosmetic surgery) but only if the later complication represents a separate medical condition such as a systemic infection, cardiac arrest, and acute drug reaction. Benefits may not be extended for any later care or a procedure related to the complication that essentially is similar to the initial non-covered care. Examples of complications similar to the initial episode of care (and thus not covered) would be repair of facial scarring resulting from dermabrasion for acne.

(ii) Benefits are available for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) and any necessary follow-on care resulting from a non-covered incident of treatment provided in an MTF, when the initial non-covered service has been authorized by the MTF Commander and the MTF is unable to provide the necessary treatment of the complications or required follow-on care, according to the guidelines adopted by the Director, DHA, or a designee.

(iii) Benefits are available for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) and any necessary follow-on care resulting from a non-covered incident of treatment provided in the private sector pursuant

to a properly granted waiver under § 199.16(f). The Director, DHA, or designee, shall issue guidelines for implementing this provision.

* * * * *

(g) * * *

(63) Non-covered condition/treatment, unauthorized provider. All services and supplies (including inpatient institutional costs) related to a non-covered condition or treatment, including any necessary follow-on care or the treatment of complications, are excluded from coverage except as provided under paragraph (e)(9) of this section. In addition, all services and supplies provided by an unauthorized provider are excluded.

* * * * *

Dated: December 22, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer,

Department of Defense.

[FR Doc. 2014-30307 Filed 12/30/2014 at 8:45 am; Publication Date: 12/31/2014]